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FROM: John E. Drach

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RE: COMPOSITE MATERIALS COMPRISED OF CALCIUM
COMPOUNDS AND PROTEIN CONSTITUENTS

Application No.: 10/030,268
Examiner: Michel Graffeo
Grp/Art Unit: 1614
Confirmation No.: 9035
Customer # 000055495

Total Pages (including this cover) 18

- Facsimile Transmittal Cover Sheet (1 page)
- Appeal Brief (17 pages)

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Art Unit 1614

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PATENT
Docket No. 223-06/H 4086 PCT/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kropf et al. Art Unit: 1614
Appl. No.: 10/030,268 Examiner: Michel Graffeo
Filed: March 19, 2002 Customer No.: 000055495
Confirm No.: 9035
Title: COMPOSITE MATERIALS COMPRISED OF CALCIUM
COMPOUNDS AND PROTEIN CONSTITUENTS

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Applicants appeal under 37 C.F.R. § 41.31 from the Final Office Action of
10/05/2006. A Notice of Appeal and payment of the appeal fee under 37 C.F.R.
§ 1.17(b) was timely filed on 12/15/2006. The Commissioner is hereby
authorized to charge \$250.00, the fee for the filing of this Brief, to Deposit
Account No. 160750.

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I. Real Party In Interest

The real party in interest in this appeal is the assignee, Henkel
Kommanditgesellschaft auf Aktien (Henkel KGaA), Duesseldorf, Germany.

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II. Related Appeals and Interferences

There are no related appeals or interferences known to applicants, assignee, or their legal representatives that will affect or be affected by or that have a bearing on this appeal.

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III. Status of the Claims

Claims 1-15, 18, 19, 22-27, and 29-30 (cancelled)

Claims 16, 17, 20-21, 28 and 31-37 (finally rejected and being appealed).

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IV. Status of Amendments

There are no un-entered amendments.

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V. Summary of Claimed Subject Matter

Claim 16

The subject matter of independent claim 16 pertains to a composite material comprising: (a) one or more poorly water-soluble phosphate salts of calcium, fluoride salts of calcium, or fluorophosphate salts of calcium, which salts may also contain hydroxyl and/or carbonate groups, the calcium salt or salts being in the form of crystalline, rodlet-like primary nanoparticles having a mean particle diameter of 10 to 300 nm; and (b) protein components selected from the group consisting of collagen, gelatine, keratin, wheat protein, rice protein, soya protein, almond protein, oat protein, pea protein, potato protein, yeast protein and hydrolyzates and hydrolyzate derivatives thereof wherein the composite is a microscopically heterogeneous aggregate of the nanoparticles associated onto the skeleton of the protein component. (Page 4, lines 1-13 and page 7, lines 1-3 of the specification).

Claim 33

The subject matter of independent claim 33 pertains to a composite material comprising: (a) one or more poorly water-soluble phosphate salts of calcium, fluoride salts of calcium, or fluorophosphate salts of calcium, which salts may also contain hydroxyl and/or carbonate groups, the calcium salt or salts being in the form of crystalline, rodlet-like primary nanoparticles having a mean particle diameter of 10 to 300 nm; and (b) a protein component wherein the protein component is gelatin and/or a hydrolyzate thereof and wherein the composite is a microscopically heterogeneous aggregate of the nanoparticles associated onto the skeleton of the protein component. (Page 4, lines 1-13 and page 7, line 13 of the specification).

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VI. Grounds of Rejection to be Reviewed on Appeal

**Whether claims 16-17, 20-21, 28 and 31-37 are unpatentable under 35
U.S.C. § 103(a) over PCT/1B97/01634 to Rudin et al. in view of US Patent
No. 4,933,173 to Bristow et al.**

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VII. Argument

Claims 16-17, 20-21, 28 and 31-37 are patentable under 35 U.S.C. § 103(a) over PCT/1B97/01634 to Rudin et al. in view of US Patent No. 4,933,173 to Bristow et al.

A. The Examiner Failed to Establish a Prima Facie Case of Obviousness.

The Examiner has not established a prima facie case of obviousness as required by law. It is well settled that the Examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness. See MPEP 2142. In attempting to make a prima facie case in the final rejection mailed on 10/05/2006, the Examiner summarized the teachings of Rudin as follows:

"Rudin et al. teach a hydroxyapatite composite comprising finely divided rod like particles of hydroxyapatite having dimensions of 60nm (L) by 15nm (W) by 5nm (T) (see page 2 paragraph 5) and a surfactant (see page 4 paragraph 4 and Example 5 which includes polyethylene glycol) which can be used to prepare toothpastes (see Abstract). Rudin et al. do not teach the incorporation of a protein, protein hydrolyzate or protein hydrolyzate derivative into the composite."

The Examiner then summarized the teachings of Bristow in an attempt to show that the claim elements missing from the teachings of Rudin are found in the teachings of Bristow as follows:

"Bristow et al. teach an oral preparation for example a toothpaste comprising hydroxyapatite and casein and explain that casein is an anti-carries agent (see col 1 lines 13-16) and additional proteins such as those from nuts (see col lines 40-50) and has a high degree of compatibility with hydroxyapatite, which is present in an amount of from 0.01% to 10% (see col 1 lines 50-55)."

The Examiner then concluded that:

"One of ordinary skill in the art would have been motivated to combine the above references because Bristow et al. teach that hydroxyapatite and casein are compatible and further that casein has anti-carries properties, both of which are reasons to add casein to a toothpaste and cause one of ordinary skill in the art to expect a better product. Thus, the claimed

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invention of the composition was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious."

The Examiner's case for *prima facie* obviousness ignores the claim limitation that the claimed composite is ***a microscopically heterogeneous aggregate of the nanoparticles associated onto the skeleton of the protein***. The Examiner has never addressed this claim limitation as required by law that the prior art references when combined must teach or suggest all the claim limitations. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The Examiner has not shown that the combination of the teachings of Rudin and Bristow teach or suggest the claim limitation that the claimed composite is ***a microscopically heterogeneous aggregate of the nanoparticles associated onto the skeleton of the protein***.

Applicants contend that neither Rudin nor Bristow alone or in combination contain any teaching about a composite material that is a microscopically heterogeneous aggregate of the nanoparticles associated onto the skeleton of the protein. In view of the foregoing arguments, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness of claims 16-17, 20-21, 28 and 31-37 over the teachings of Rudin et al. in view of Bristow et al.

B. No Motivation to Combine the Teachings of Rudin and Bristow

Assuming, arguendo, that a *prima facie* was established by the Examiner, Applicants submit that one of ordinary skill in the art would not have been motivated to combine the teachings of Rudin and Bristow at the time the instant

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invention was made because Bristow teaches away from such a combination. More specifically, Bristow teaches a substantially fluorine free anti-caries oral composition comprising finely-divided hydroxyapatite and an anti-caries agent selected from water-soluble casein materials and sodium trimetaphosphate at column 1, line 67 to column 2, line 3. A person of ordinary skill in the art, upon reading the teachings of Bristow, would be discouraged from combining casein and fluorine-containing materials in making an anti-caries oral composition. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. In re Gurley, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994). In rebuttal to the above position, the Examiner argued that

"since Bristow et al. discuss a toothpaste substantially free of fluoride does not mean that the fluoride if used in Rudin et al. is uncombinable especially in light of the product made, toothpaste, and that fluoride is typically used in toothpastes. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made".

Applicants respond that the legal standard is not whether an element of the prior art is physically combinable with another element of the prior art but whether one of ordinary skill in the art would have been motivated to combine the teachings of separate pieces of prior art at the time that the invention was made. In the present case, Applicants do not allege that fluoride is physically uncombinable with combinations taught by Rudin but that the teachings of Bristow would have discouraged one of ordinary skill in the art at the time that the instantly claimed invention was made from combining the teachings of Bristow with those of Rudin.

C. The Examiner Failed to Consider the Invention as a Whole.

In making the obviousness rejection, the Examiner has not considered the instantly claimed subject matter as a whole which includes the limitation that the claimed composite is *a microscopically heterogeneous aggregate of the nanoparticles associated onto the skeleton of the protein*. It is well settled that a claimed invention is unpatentable for obviousness if the differences between it and the prior art are such that the subject matter as a whole would have been

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obvious at the time the invention was made to a person having ordinary skill in the art. In re Zurko, 258 F.3d 1379, 59 USPQ2d 1693, 1696 (Fed. Cir. 2001). There is nothing in the record of the prosecution of the instant application that shows that the Examiner ever addressed the limitation that the claimed composite is a *microscopically heterogeneous aggregate of the nanoparticles associated onto the skeleton of the protein*. The record also fails to show where in the Rudin and/or the Bristow reference it is taught or suggested that the claimed composite is a *microscopically heterogeneous aggregate of the nanoparticles associated onto the skeleton of the protein*.

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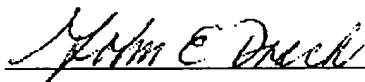
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CONCLUSION

For the reasons stated above, Applicants respectfully submit the Examiner's final rejection of claims 16, 17, 20-21, 28 and 31-37 should be reversed. Should any fees be due for entry and consideration of this brief that have not been accounted for, the Commissioner is authorized to charge them to Deposit Account No. 160750.

Respectfully submitted,



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VII. CLAIMS APPENDIX

16. A composite material comprising: (a) one or more poorly water-soluble phosphate salts of calcium, fluoride salts of calcium, or fluorophosphate salts of calcium, which salts may also contain hydroxyl and/or carbonate groups, the calcium salt or salts being in the form of crystalline, rodlet-like primary nanoparticles having a mean particle diameter of 10 to 300 nm; and (b) protein components selected from the group consisting of collagen, gelatine, keratin, wheat protein, rice protein, soya protein, almond protein, oat protein, pea protein, potato protein, yeast protein and hydrolyzates and hydrolyzate derivatives thereof wherein the composite is a microscopically heterogeneous aggregate of the nanoparticles associated onto the skeleton of the protein component.

17. The composite material of claim 16 wherein the rodlet-like primary particles have a thickness of 2 to 50 nm and a length of 10 to 150 nm.

20. The composite material of claim 16, wherein the calcium salts are encapsulated with one or more surface modifiers.

21. The composite material of claim 16, wherein the calcium salts comprise one or more hydroxylapatite or fluorapatite salts.

28. A toothpaste comprising the composite material of claim 16.

31. The composite material of claim 16, wherein b) comprises 0.1% to 60% by weight of the composite material.

32. The composite material of claim 31, wherein b) comprises 0.5% to 10% by weight of the composite material.

33. A composite material comprising: (a) one or more poorly water-soluble phosphate salts of calcium, fluoride salts of calcium, or fluorophosphate salts of

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calcium, which salts may also contain hydroxyl and/or carbonate groups, the calcium salt or salts being in the form of crystalline, rodlet-like primary nanoparticles having a mean particle diameter of 10 to 300 nm; and (b) a protein component wherein the protein component is gelatin and/or a hydrolyzate thereof and wherein the composite is a microscopically heterogeneous aggregate of the nanoparticles associated onto the skeleton of the protein component.

34. The composite material of claim 33 wherein the calcium salts are encapsulated with one or more surface modifiers.

35. The composite material of claim 33 wherein the calcium salts comprise one or more hydroxylapatite or fluorapatite salts.

36. The composite material of claim 33 wherein the rodlet-like primary particles have a thickness of 2 to 50 nm and a length of 10 to 150 nm.

37. A toothpaste comprising the composite material of claim 33.

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IX. EVIDENCE APPENDIX

There is no evidence entered by the Examiner and relied upon by the
Appellant in this Appeal.

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X. RELATED PROCEEDINGS APPENDIX

There are no relevant judicial or administrative decisions to provide.